K083654 1/2

## Summary of Safety and Effectiveness

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| **Submitter:** | Zimmer, Inc.<br>P.O. Box 708<br>Warsaw, IN 46581-0708<br>FEB 2 6 2009 |
| **Contact Person:** | Anthony Francalancia, RAC<br>Senior Associate, Regulatory Affairs<br>Telephone: (574) 372-4570<br>Fax: (574) 372-4605 |
| **Date:** | December 5, 2008 |
| **Trade Name:** | *Zimmer*® Universal Locking System: 2.7 mm Locking Plates and Screws (*Tivanium*® Ti-6Al-4V Alloy, CP Grade Titanium) |
| **Common Name:** | 2.7mm TiULS Locking Plate System |
| **Classification Name and Reference:** | Plate, Fixation, Bone (21 CFR § 888.3030)<br>Screw, Fixation, Bone (21 CFR § 888.3040) |
| **Predicate Device:** | *Zimmer* Universal Locking System, 2.7mm Plates and Screws, manufactured by Zimmer, Inc., K063303, cleared November 22, 2006 |
| **Device Description:** | The *Zimmer* Universal Locking System is a plate and screw system intended for internal fracture fixation. The plate selection consists of dual compression, reconstruction, tubular, straight "T" and "L" plate configurations. Plates accommodate either standard or locking screws via figure-8 shaped holes. |
| **Intended Use:** | The Universal Locking System is indicated for temporary internal fixation and stabilization of osteotomies and fractures, including:<br>o Comminuted fractures<br>o Supracondylar fractures<br>o Extra-articular fractures<br>o Fractures in osteopenic bone<br>o Nonunions<br>o Malunions |

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| **Comparison to Predicate Device:** | The *Zimmer* Universal Locking System: 2.7mm plates and screws have the same intended use, similar performance characteristics and are similar in design to the predicate devices. |
| **Performance Data (Nonclinical and/or Clinical):** | Non-Clinical Performance and Conclusions:<br><br>The results of non-clinical (laboratory) performance testing demonstrate that the device is safe and effective. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Zimmer, Inc.
% Mr. Anthony Francalancia
P.O. Box 708
Warsaw, Indiana 46581-0708

FEB 2 6 2009

Re: K083654
Trade/Device Name: Zimmer Universal Locking System: 2.7 mm Locking Plates and Screws (Tivanium Ti-6Al-4V Alloy, CP Grade Titanium)
Regulation Number: 21 CFR 888.3730
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories.
Regulatory Class: II
Product Code: HRS, HWC
Dated: February 3, 2009
Received: February 4, 2009

Dear Mr. Francalancia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

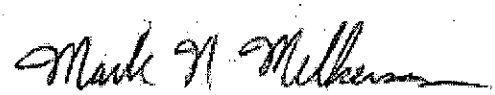
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):**

**Device Name:** K083654

*Zimmer*® Universal Locking System: 2.7 mm Locking Plates and Screws (*Tivanium*® Ti-6Al-4V Alloy, CP Grade Titanium)

**Indications for Use:**

The Universal Locking System is indicated for temporary internal fixation and stabilization of osteotomies and fractures, including:

- Comminuted fractures
- Supracondylar fractures
- Extra-articular fractures
- Fractures in osteopenic bone
- Nonunions
- Malunions

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K083654